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Bielefeld

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(54) **ADJUSTABLE ANNULOPLASTY RING SIZING INDICATOR**

(75) Inventor: **Eric E. Bielefeld**, Floyds Knobs, IN (US)

(73) Assignee: **St. Jude Medical, Inc.**, St. Paul, MN (US)

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B25G 3/18	(2006.01)
B25B 23/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/2466*** (2013.01); ***A61F 2/2496*** (2013.01); ***B25B 23/0064*** (2013.01); ***B25G 3/18*** (2013.01); *A61F 2250/001* (2013.01)

(58) **Field of Classification Search**

CPC A61F 2/2448; A61F 2/2451; A61F 2/2466
USPC 623/2.36, 2.37
See application file for complete search history.

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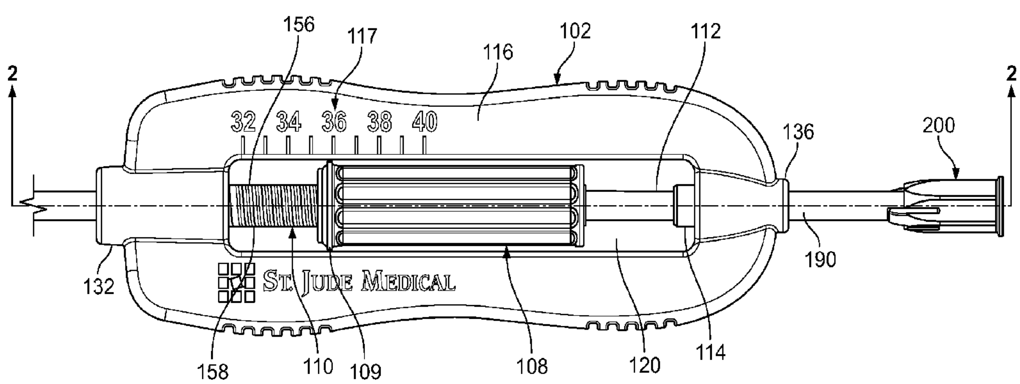
Primary Examiner — Jason-Dennis Stewart
(74) *Attorney, Agent, or Firm* — Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) **ABSTRACT**

An adjustment tool enables manipulation of a prosthetic anatomical device such as an annuloplasty ring. The tool includes a compression member which is operative for retarding rotation of the adjustment shaft to preclude inadvertent rotation thereof during use of the tool by the surgeon. A locking device is associated with the adjustment tool to enable the releasable attachment of the tool to the anatomical device during its adjustment by manipulation of the tool. The locking device is oriented into operative and inoperative positions by the engagement and disengagement of locking elements. A scale may be provided on the adjustment tool to assist a surgeon in determining the size or amount of adjustment to the size of the anatomical device during its adjustment.

30 Claims, 9 Drawing Sheets



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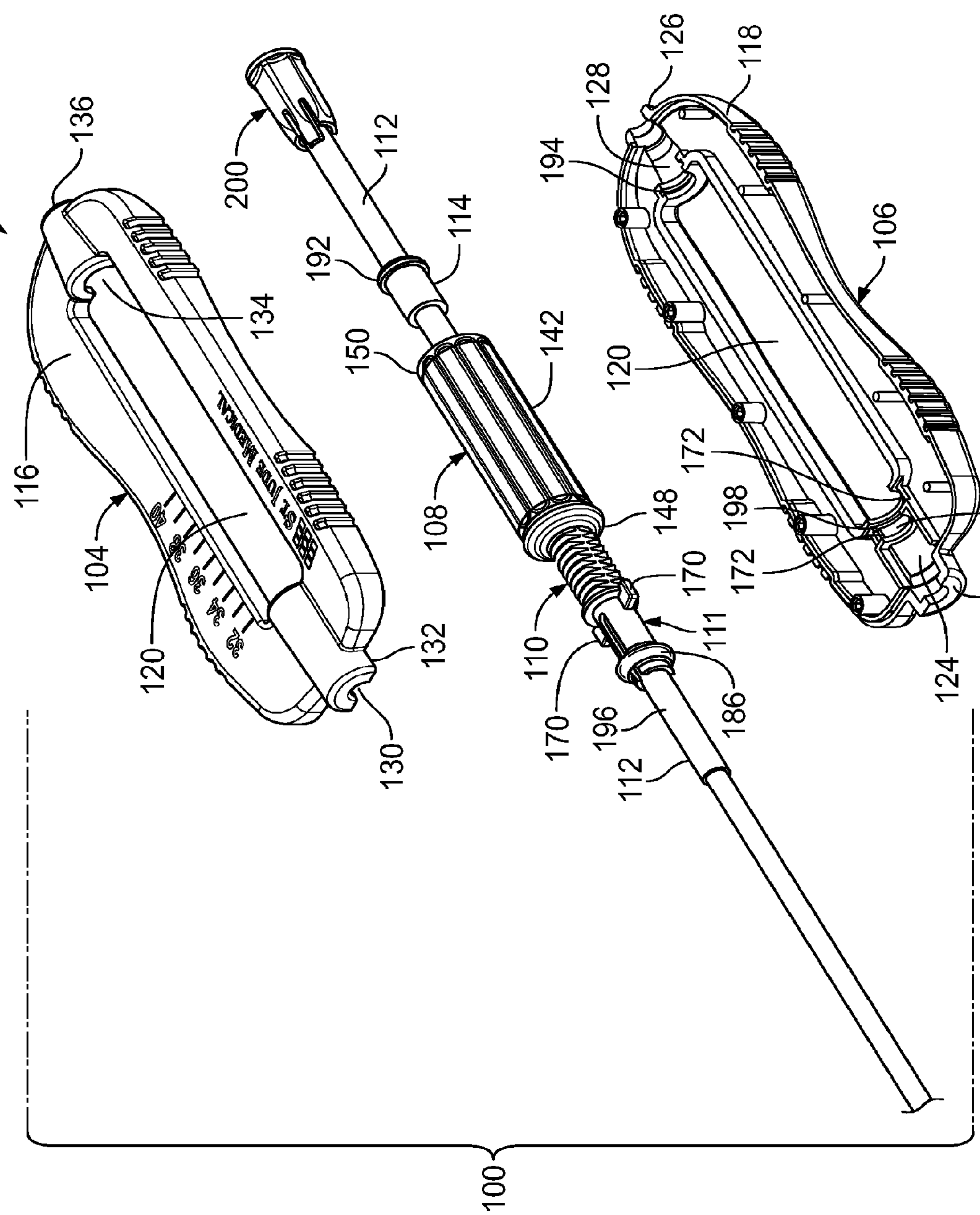
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FIG. 1

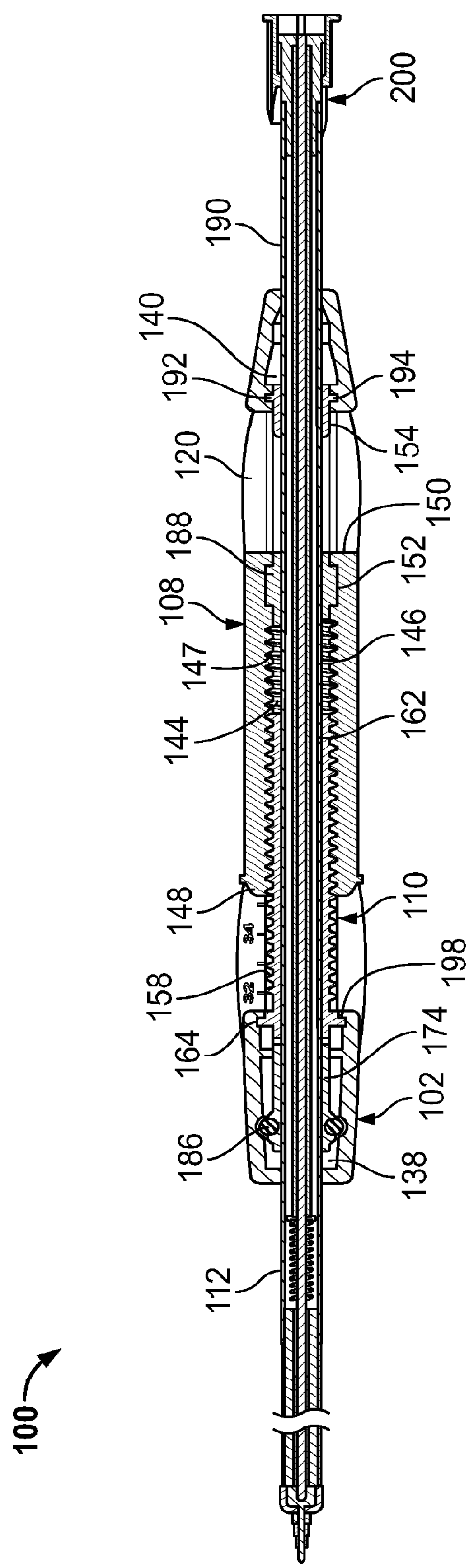
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FIG. 2

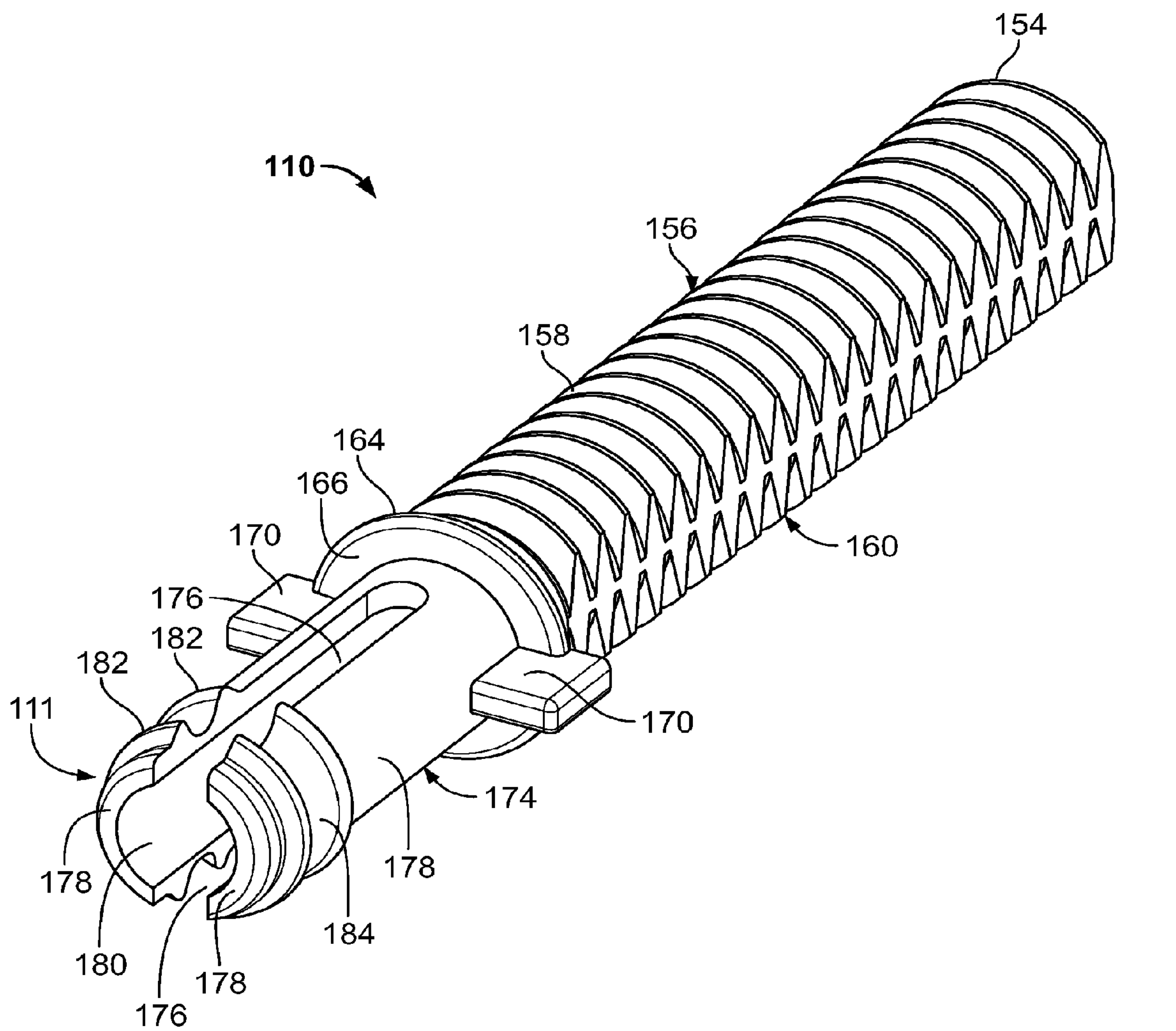
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FIG. 3

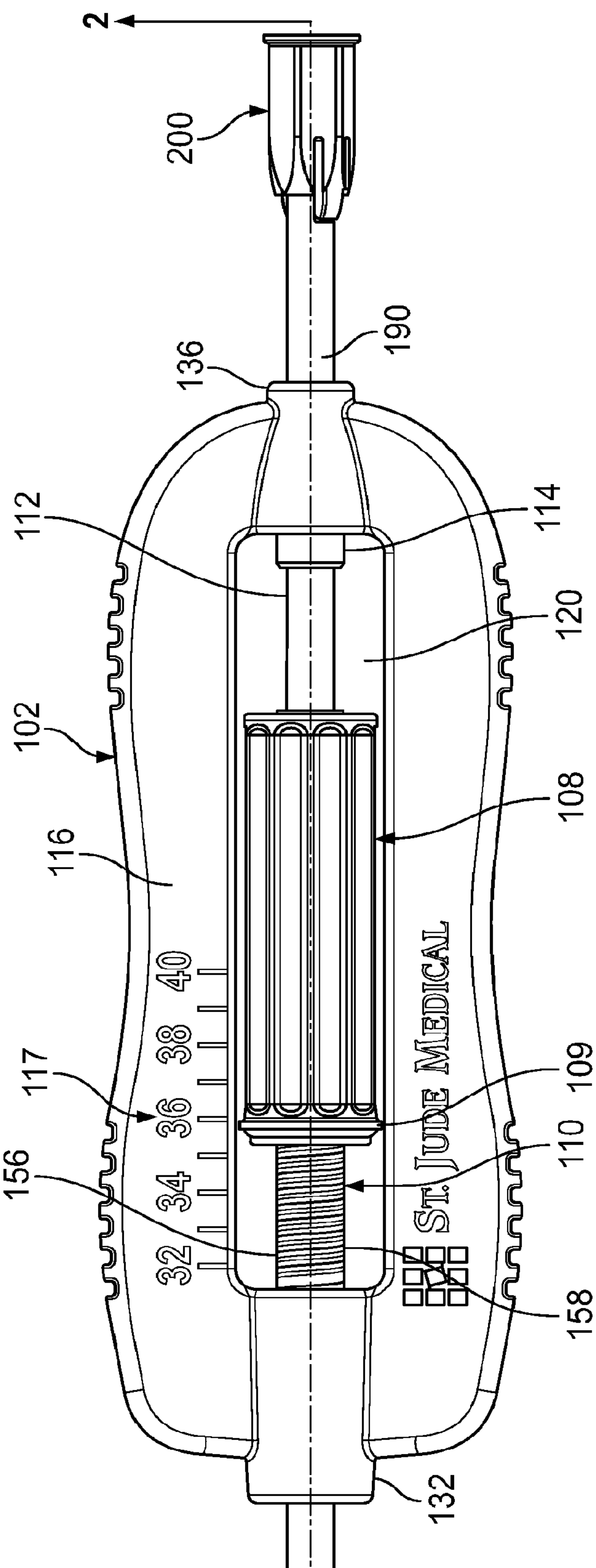
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FIG. 4

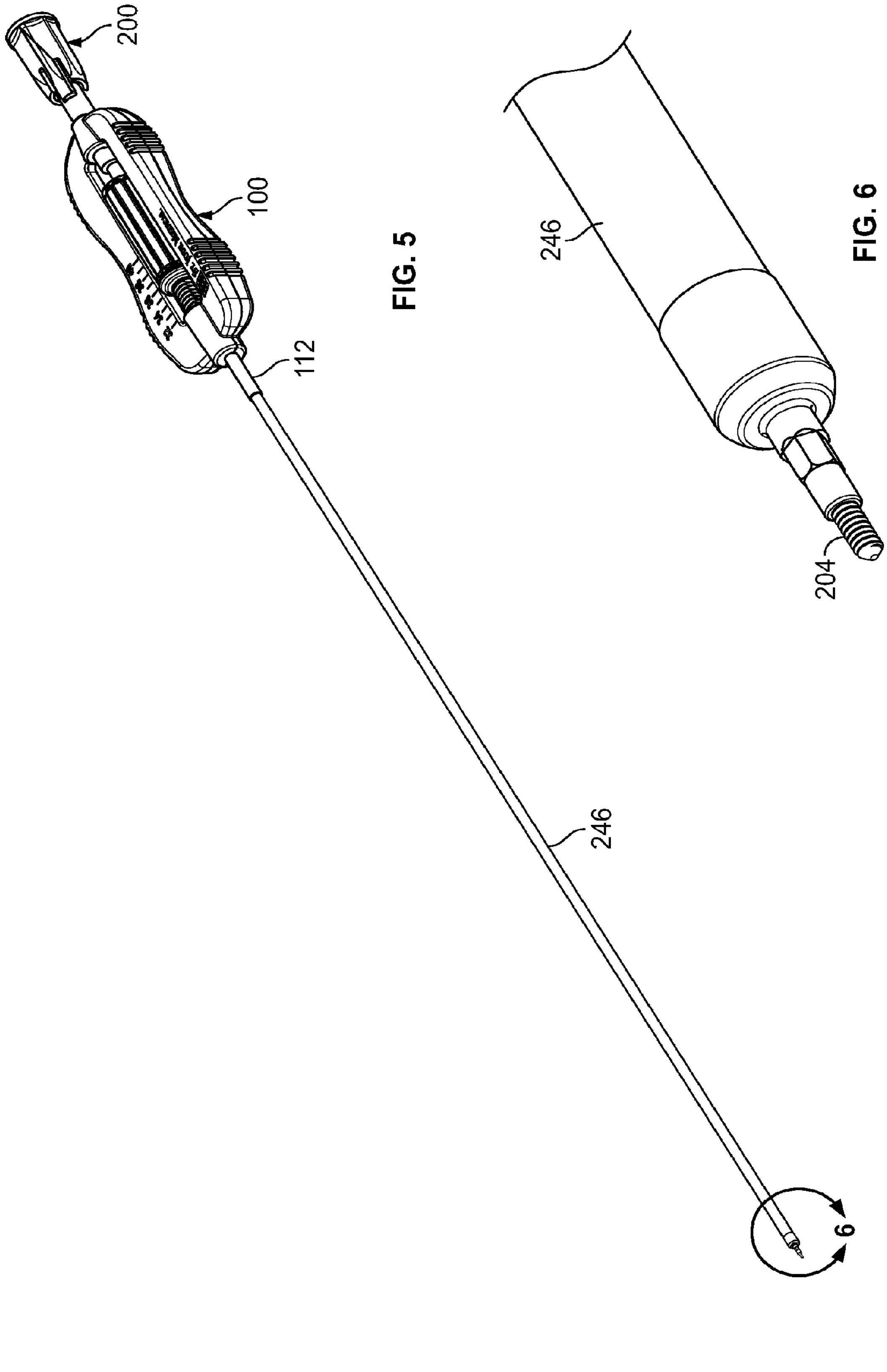

FIG. 5

FIG. 6

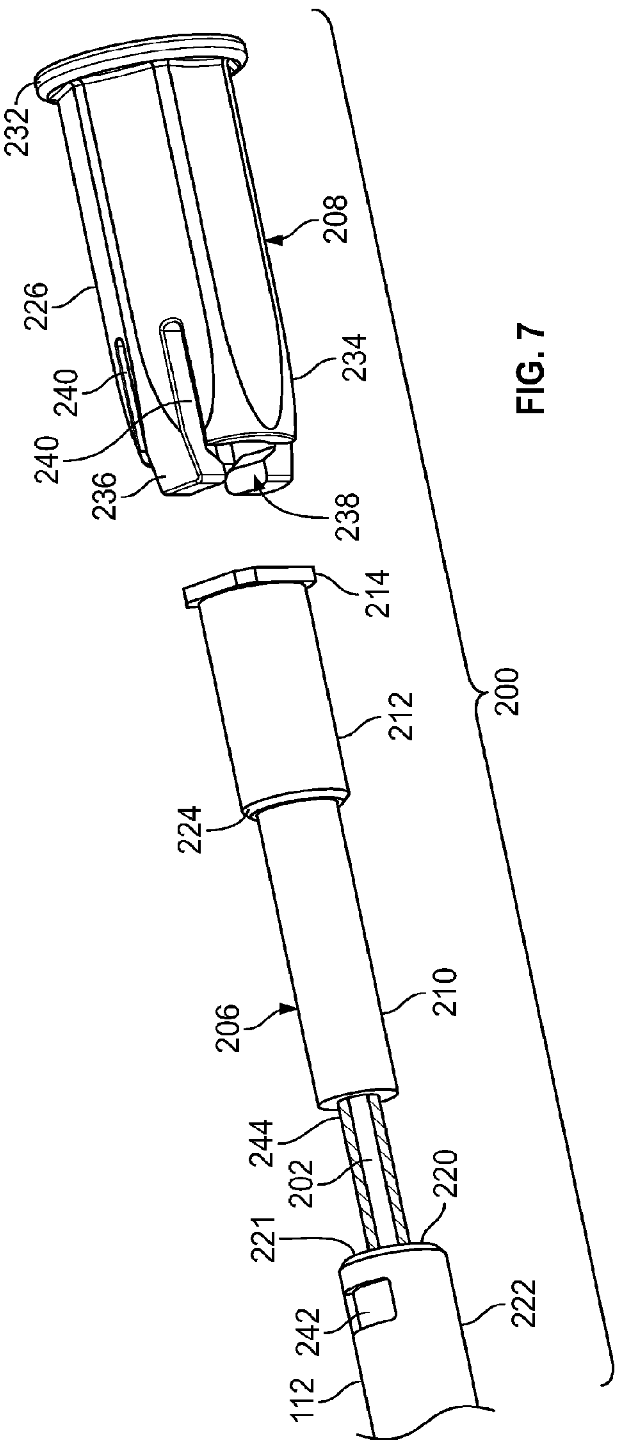
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FIG. 7

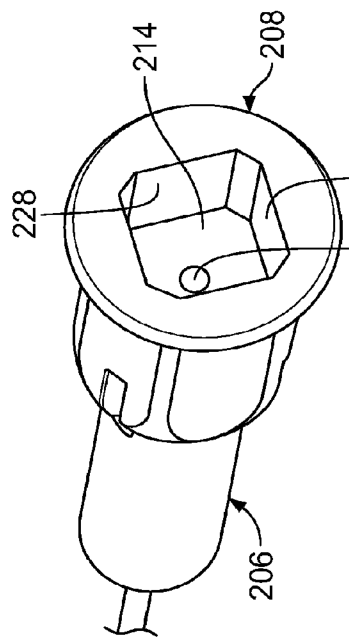
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FIG. 8

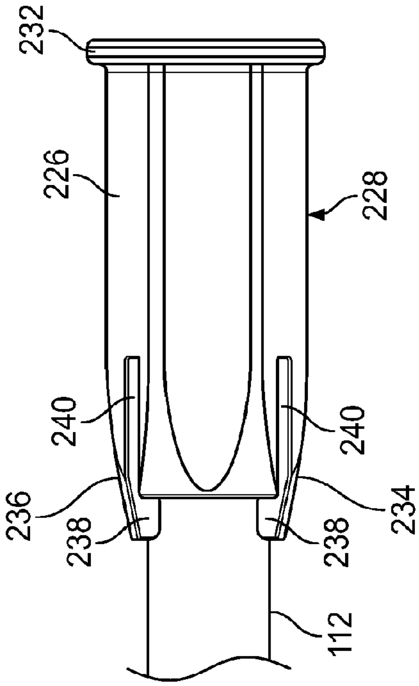

FIG. 11

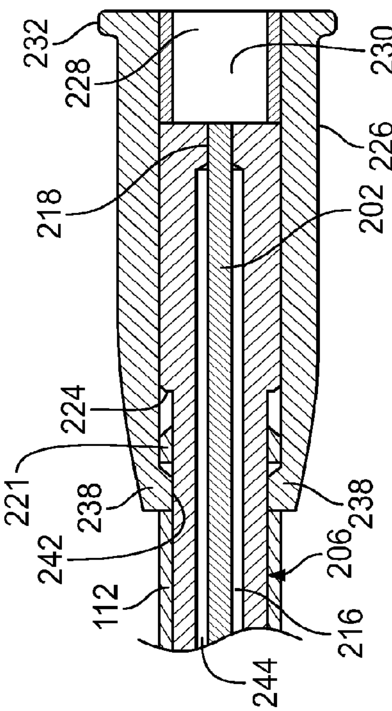

FIG. 12

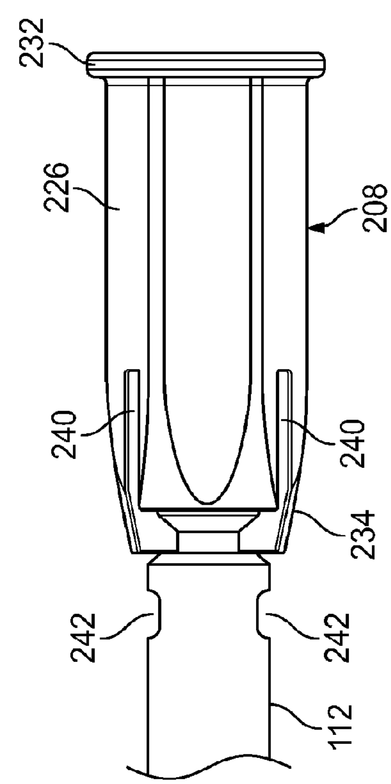

FIG. 9

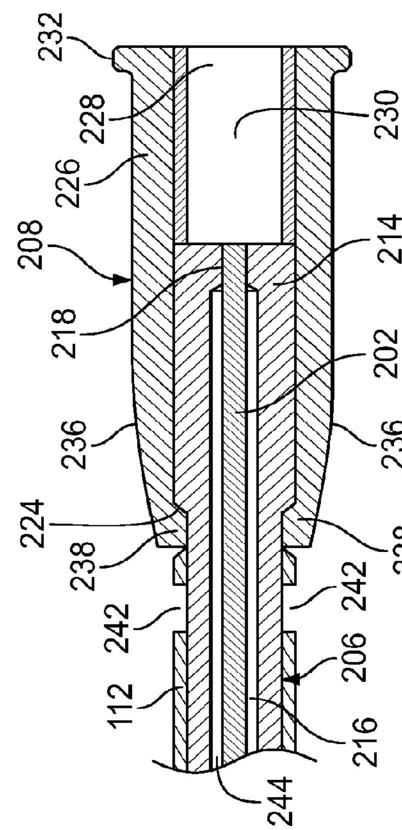

FIG. 10

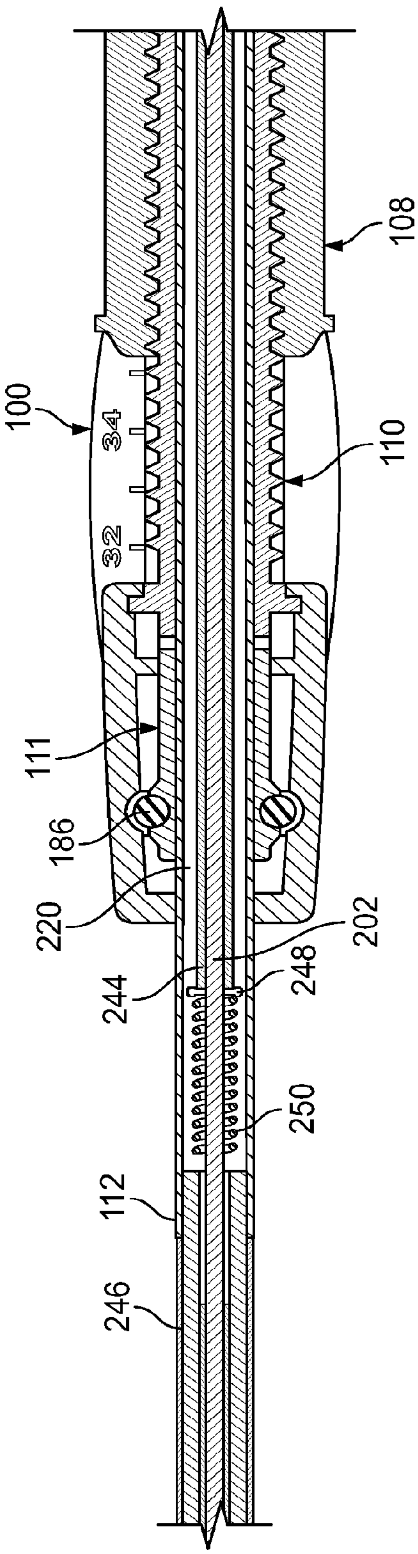
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FIG. 13

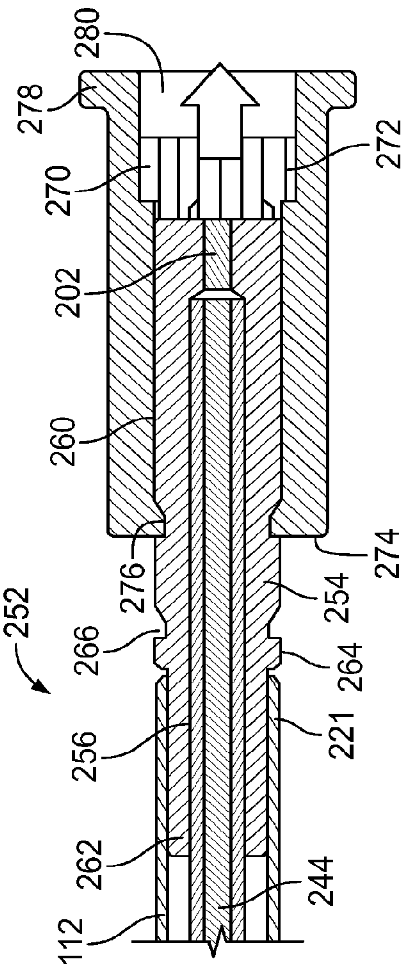
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FIG. 14

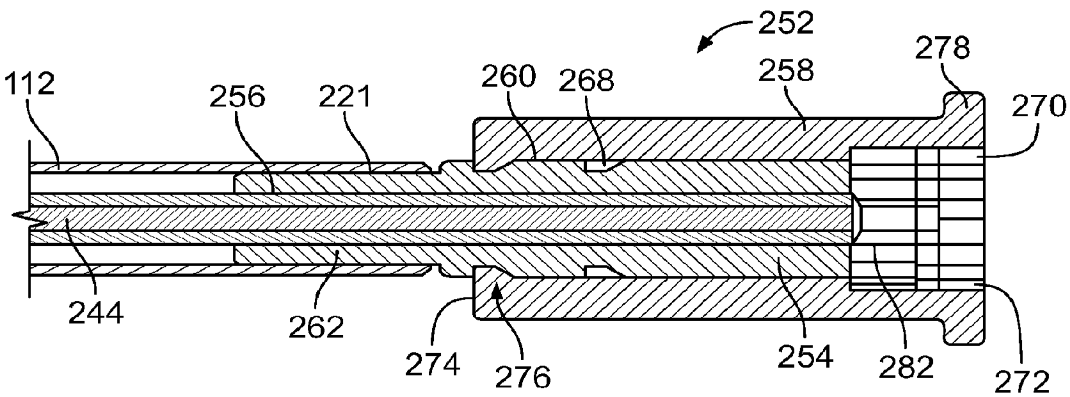

FIG. 15

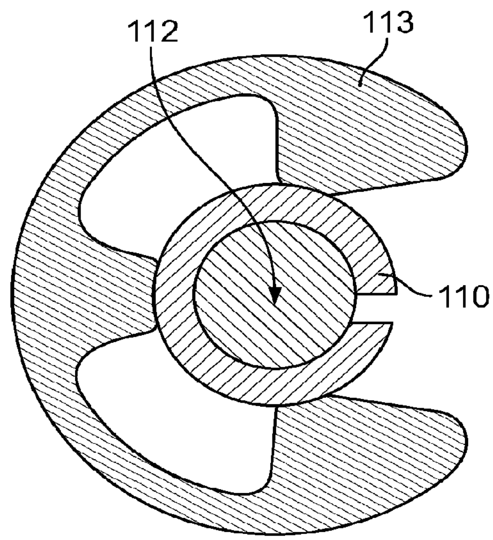

FIG. 16

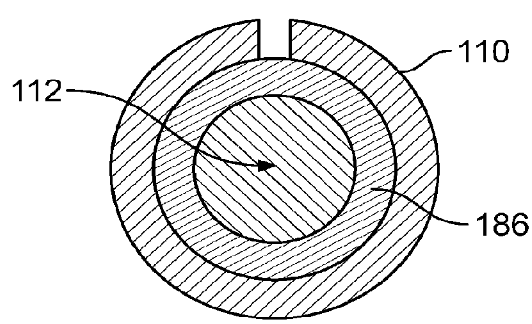

FIG. 17

ADJUSTABLE ANNULOPLASTY RING SIZING INDICATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of the filing dates of U.S. Provisional Patent Application No. 61/438,129 filed Jan. 31, 2011 and of U.S. Provisional Patent Application No. 61/527,812 filed Aug. 26, 2011, the entire disclosures of which are each hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates in general to a tool for adjusting a prosthetic anatomical device, and more particularly, to a tool for adjusting the Seguin size and/or shape of an implantable device.

Heart valve disease is a condition in which one or more valves of the heart fail to function properly. Diseased heart valves may be categorized as either stenotic, wherein the valve does not open sufficiently to allow adequate forward flow of blood through the valve, or incompetent, wherein the valve does not close completely causing excessive backward flow of blood through the valve when the valve is closed.

By way of one specific example, the mitral valve is the inflow valve for the left side of the heart. Blood flows from the lungs, where it picks up oxygen, through the pulmonary veins, to the left atrium of the heart. After the left atrium fills with blood, the mitral valve allows blood to flow from the left atrium into the heart's main pumping chamber called the left ventricle. It then closes to keep blood from leaking back into the left atrium or lungs when the left ventricle contracts to push blood out to the body.

Valve disease relating to the mitral valve often involves secondary mitral regurgitation which is the backward flow of blood from the left ventricle to the left atrium resulting from imperfections in the mitral valve. One repair technique for treating regurgitation is called annuloplasty, in which the size and/or shape of the valve annulus is modified by securing a prosthetic adjustable annuloplasty ring to an interior wall of the heart around the valve annulus. The size and/or shape of the annuloplasty ring is adjusted in situ for maintaining coaptation to prevent reversed blood flow.

Examples of an adjustable annuloplasty ring are disclosed in United States Patent Application Publication No. 2011/0066231, the disclosure of which is incorporated herein by reference. The disclosed annuloplasty ring includes an adjustment assembly for expanding or contracting the Seguin size of the opening formed by the ring. A suitable tool is also disclosed to engage the adjustment assembly to enable adjustment of the annuloplasty ring in situ once implanted into a patient.

SUMMARY OF THE INVENTION

The present invention discloses a minimally invasive adjustment tool having enhanced features to enable the in situ adjustment of an annuloplasty ring or other prosthetic anatomical device after being implanted into a patient.

In accordance with one embodiment, the adjustment tool of the present invention incorporates a hand held handle which rotationally supports a center shaft or hypotube which is operative for adjusting the opening or Seguin size and/or shape of an adjustable device, for example, an anatomical structure such as an annuloplasty ring. The hypotube is rotated by an internally threaded knob received about an externally threaded cylinder. The knob is accessible to the surgeon through an enlarged opening within the handle. A compression member is arranged within the housing for engaging a portion of the hypotube for retarding its unrestricted rotation when the tool is being used for adjustment of an anatomical device such as an annuloplasty ring and the like.

In accordance with a further embodiment of the present invention, the tool can incorporate a rotational locking device which is adapted for releasably attaching the tool to the prosthetic anatomical device to be adjusted. The locking device incorporates an elongated shaft having a threaded end received within the hypotube, and optionally within a second hypotube concentrically arranged within the first hypotube. A knob is coupled to one end of the first hypotube and attached to an end of the shaft. A sleeve is slideably engaged about the knob in keyed relationship between a first and second position. The first hypotube adjacent its proximal end is provided with a first locking element and the sleeve is provided with a second locking element. Movement of the sleeve to the first position engages the locking elements thereby precluding rotation of the sleeve and preventing rotation of the shaft. Movement of the sleeve to the second position disengages the first and second locking elements whereby rotation of the sleeve causes rotation of the shaft and its threaded end relative to the anatomical device.

In accordance with a further embodiment of the invention, the adjustment tool includes a housing having a scale thereon. A knob is rotatably disposed within the housing. A shaft is coupled to the knob for rotation therewith and includes a distal end adapted to engage a prosthetic anatomical device, for example, an adjustable annuloplasty ring. A pointer is arranged on the knob to indicate the size of the adjustable annuloplasty ring corresponding to the scale aligned with the pointer. In different illustrative embodiments, the scale may be a Seguin sizing scale, may indicate the outer diameter of the adjustable annuloplasty ring, or may include a plurality of symbols indicating the magnitude of the displacement of the pointer with respect to the scale. The pointer is arranged adjacent a distal end of the knob, and comprises a band at least partially circumscribing the knob. The scale may be printed on the housing and/or molded into the housing.

According to a further embodiment, the adjustment tool includes a threaded barrel coupled to the housing. The knob includes internal threads adapted to engage the threaded barrel such that rotation of the knob relative to the threaded barrel causes the knob to move longitudinally with respect to the barrel. The adjustment tool also includes an elongated hypotube arranged substantially concentrically about the shaft.

In accordance with a further embodiment of the invention, the adjustment tool includes a housing having a scale thereon. The housing includes a proximal end and a distal end. A threaded barrel is coupled to the housing and extends along at least a portion of the length of the housing. A knob is rotatably disposed about the threaded barrel and has threads adapted to engage the threaded barrel. A shaft extends within the knob and is supported within the housing. The shaft is coupled to the knob for rotation with the knob. An adjustment head is arranged on a distal end of the shaft. The adjustment head is adapted to engage a prosthetic anatomical device, for example, an adjustable annuloplasty ring. A pointer is arranged on the knob and adapted to align with the scale.

In accordance with another embodiment of the invention, a method of adjusting the size of a prosthetic anatomical device, for example, an adjustable annuloplasty ring, is provided. In one embodiment, the method includes engaging an adjustable annuloplasty ring with an adjustment tool. The adjustment tool includes a housing having a scale thereon, a knob rotatably disposed within the housing, a pointer arranged on the knob to align with the scale, and a shaft coupled to the knob for rotation therewith. The shaft includes a distal end adapted to engage the adjustable annuloplasty ring. The method further includes moving the knob relative to the housing such that the pointer aligns with the scale and determining the size of the adjustable annuloplasty ring corresponding to the scale with which the pointer aligns.

In accordance with a further embodiment of the invention, the method also includes disengaging the adjustment tool from the adjustable annuloplasty ring when the size of the adjustable annuloplasty ring corresponds to a predetermined desired size. The method further includes moving the knob relative to the housing to adjust the size of the adjustable annuloplasty ring after determining the size of the adjustable annuloplasty ring if the size of the adjustable annuloplasty ring does not correspond to a predetermined desired size. In one embodiment, the scale is a Seguin sizing scale. In another embodiment, the pointer indicates the outer diameter of the adjustable annuloplasty ring corresponding to the scale aligned with the pointer.

In accordance with a still further embodiment of the invention, the method includes engaging an adjustable annuloplasty ring with an adjustment tool. The adjustment tool includes a housing having a scale thereon. The housing includes a distal end and a proximal end. A threaded barrel is coupled to the housing and a knob is rotatably disposed about the threaded barrel. The knob includes threads adapted to engage the threaded barrel. A shaft extends within the knob supported within the housing. The shaft may be coupled to the knob for rotation therewith. An adjustment head is arranged on the shaft and is adapted to engage the adjustable annuloplasty ring. A pointer is arranged on the knob and adapted to align with the scale. The method also includes rotating the knob such that the shaft and the adjustment head thereof rotate with respect to the threaded barrel and such that the knob is displaced along a longitudinal direction of the threaded barrel. The method further includes determining the adjustment to the size of the adjustable annuloplasty ring resulting from the rotation of the adjustment head and location of the pointer relative to the scale resulting from the displacement of the knob.

In accordance with a further embodiment, the method includes disengaging the adjustment tool from the adjustable annuloplasty ring when the size of the adjustable annuloplasty ring corresponds to a predetermined desired size.

In accordance with yet another embodiment, the method includes moving the knob relative to the housing to adjust the size of the adjustable annuloplasty ring if the size of the adjustable annuloplasty ring does not correspond to a predetermined desired size.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter regarded as the invention is particularly pointed out and distinctly claimed in the concluding portion of the specification. The invention, however, both as to organization and method of operation, together with features, objects and advantages thereof may best be understood by reference to the following detailed description when read with the accompanying drawings in which:

FIG. **1** is an exploded perspective view showing the components of an adjustment tool in accordance with one embodiment of the present invention in a partially assembled arrangement.

FIG. **2** is a cross-sectional view of the assembled adjustment tool taken along line **2-2** in FIG. **4**.

FIG. **3** is a perspective view of an elongated externally threaded barrel forming one component of the adjustment tool.

FIG. **4** is a top plan view of the assembled adjustment tool as shown in FIG. **1**.

FIG. **5** is a perspective view of the assembled adjustment tool coupled to an elongated shaft having its distal end constructed to operatively engage an adjustment mechanism on an annuloplasty ring.

FIG. **6** is an enlarged perspective view of the distal end of the adjustment tool shaft constructed to operatively engage the adjustment mechanism of an annuloplasty ring.

FIG. **7** is an exploded perspective view showing the components of a rotational locking device in accordance with one embodiment of the present invention in a disassembled arrangement.

FIG. **8** is a perspective view showing the assembly of the proximal end of the rotational locking device as shown in FIG. **10**.

FIG. **9** is a front elevational view of an assembled rotational locking device as shown in FIG. **7** arranged in an unlocked position.

FIG. **10** is a cross-sectional view of the assembled rotational locking device as shown in FIG. **9** in an unlocked position.

FIG. **11** is a front elevational view of an assembled rotational adjustment device as shown in FIG. **7** in a locked position.

FIG. **12** is a cross-sectional view of the assembled rotational locking device as shown in FIG. **11** in a locked position.

FIG. **13** is a cross-sectional view of the distal end of an adjustment tool incorporating a rotational locking device in accordance with one embodiment of the present invention.

FIG. **14** is a cross-sectional view of a rotational locking device in accordance with another embodiment of the present invention shown in a locked position.

FIG. **15** is a cross-sectional view of the rotational locking device of FIG. **14** shown in an unlocked position.

FIG. **16** is a cross-sectional view of a barrel in engagement with the elongated shaft and a fastener along a longitudinal axis thereof in accordance with one embodiment of the present invention.

FIG. **17** is a cross-sectional view of an o-ring in engagement with an elongated shaft and a barrel a longitudinal axis thereof in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION

In describing the preferred embodiments of the invention illustrated in the drawings, specific terminology will be used for the sake of clarity. However, the invention is not intended to be limited to the specific terms so used, and it is to be understood that each specific term includes all equivalence that operate in a similar manner to accomplish a similar purpose.

As used herein, the terms “proximal” and “distal” are to be taken as relative to a user (e.g., a surgeon) using the disclosed device. “Proximal” is to be understood as relatively close to the user and “distal” is to be understood as relatively farther away from the user.

Referring to the drawings, wherein like reference numerals represent like elements, there is shown in FIG. **1** an adjustment tool **100** constructed in accordance with one embodiment of the present invention. The adjustment tool **100** in the illustrated embodiment is constructed generally to include a housing **102** formed from a first housing half **104** and a mating second housing half **106**; an elongated knob **108**; an elongated cylinder such as a barrel **110**; a compression member **111**; an elongated central shaft **112** such as an elongated hypotube; and an optional bushing **114**. A detailed description of the aforementioned components of the adjustment tool **100** and their assembled relationship will now be described.

Referring to FIGS. **1** through **4**, the first and second housing halves **104**, **106** which form the housing **102** are generally constructed as complimentary elongated annular shaped hollow shells **116**, **118**. When assembled, the housing halves **104**, **106** form a central elongated opening **120**. The first housing half **104** is provided with a through bore **130** at its distal end **132**, and a through bore **134** at its proximal end **136**. In a complimentary construction, the second housing half **106** at its distal end **122** is formed with a through bore **124**, and at its proximal end **126** with a through bore **128**. The assembled relationship of the first and second housing halves **104**, **106** is best shown in FIG. **2**. When assembled to form the housing **102**, corresponding bores **124**, **130** at the distal ends **122**, **132** of the housing halves form a central bore **138**. Likewise, the corresponding bores **128**, **134** at the proximal ends **126**, **136** of the housing halves form a central bore **140**. As previously described, the first and second housing halves **104**, **106**, when assembled, form the elongated central opening **120** within the adjustment tool **100** in communication with each of the bores **138**, **140**.

The knob **108** can be constructed as an elongated cylindrical body **142** having a central longitudinally extending through bore **144** surrounded by a threaded portion **146** formed from a plurality of threads **147**. The threaded portion **146** generally extends from the distal end **148** of the knob **108** to adjacent its proximal end **150**. An annular internal recess **152** is formed circumscribing the bore **144** adjacent the proximal end **150** of the knob. The outer surface of the knob **108** may be textured to provide a friction or irregular surface to facilitate rotation of the knob by the surgeon's fingers during use of the adjustment tool **100**.

The barrel **110** as best shown in FIG. **3** can be formed as an elongated cylindrical body **154** having an externally threaded portion **156** formed by a plurality of threads **158**. The threaded portion **156** may have one or more flatten regions **160** extending longitudinally along the length of the barrel at one or more circumferential locations. The flatten region functions to facilitate the molding process when forming the barrel **110** from polymer compositions. A bore **162** extends longitudinally through the center of the body **154**. A large diameter circumscribing ring **164** can be provided at the distal end **166** of the body **154**. The ring **164** is captured within a corresponding confining opening **168** provided within the distal end of the adjustment tool **100** for securing the barrel **110** and preventing its longitudal movement within the housing **102**.

One or more protrusions **170** in the nature of flanges or other such structures may be provided extending radially outward about a circumferential portion of the distal end **166** outwardly of the ring **164**. In accordance with one embodiment as illustrated in FIG. **3**, two protrusions **170** are arranged opposing one another extending outwardly. The protrusions **170** are adapted to be received within confining notches **172** formed by the mating first and second housing halves **104**, **106** adjacent the opening **168**. The protrusions **170** by being captured within the notches **172** prevent rotation of the barrel **110** during use of the tool **100**, while the ring **164** prevents longitudal movement of the barrel within the opening **120** formed within the housing **102**.

Although the protrusions **170** have been described as flanges, the protrusions may take any other shape or form which functions to cooperate with the housing **102** to prevent rotation of the barrel. In addition, although two protrusions **170** have been illustrated, it is contemplated that only one protrusion would be sufficient to prevent rotation of the barrel. Further, any greater number of protrusions **170** can be provided, such as three or more protrusions in the form of flanges or other structures as thus far described and contemplated.

The compression member **111** is arranged extending longitudinally outwardly from the distal end **166** of the barrel **110**. The compression member **111**, in accordance with one embodiment, is constructed from an elongated cylindrical body **174** having one or more circumferentially arranged elongated slots **176** dividing the body into a plurality of elongated flexible members **178** in the nature of finger like appendages. A through bore **180** is provided longitudinally through the compression member **111** in communication with the bore **162** provided within the barrel **110**. The inner surfaces of the members **178** may be shaped and sized to conform to and be arranged in surface contact with the outer surface of the central shaft **112**. The primary function of the compression member **111** is to retard rotation of the central shaft **112** so as to prevent its free unintended rotation during use of the adjustment tool **100** by creating frictional engagement of the members **178** with the central shaft. This can be accomplished, in one embodiment, by providing one or more elongated slots **176** which enable each member **178** to be sufficiently flexible so as to be arrangeable in compressive engagement with the central shaft **112**.

The compression member **111** may be constructed to include any number of elongated members **178** by providing one or more elongated slots **176**. Although two slots **176** are illustrated, it is contemplated that a single slot would be sufficient to provide the body **174** with sufficient flexibility to be compressively engaged about the shaft **112** to retard its rotation. Further by way of example, three elongated members **178** may be provided by incorporating three elongated slots **176** arranged circumferentially about the cylindrical body **174**. It is not required that the slots **176** be equally spaced circumferentially about the body **174**.

Compression of the elongated members **178** against the central shaft **112** may be accomplished in a number of ways. In the preferred embodiment, the end of the cylindrical body **174** can be provided with a pair of spaced apart circumscribing ribs **182** forming an annular opening **184** therebetween. A resilient o-ring **186** can be received within the annular opening **184** to provide a uniform inward compressive force of the elongated members **178** against the external surface of the central shaft **112**. The degree of force applied by the o-ring **186** can be predetermined by the relative size of the o-ring to that of the annular opening **184**. Accordingly, one can design the compression member **111** to apply a predetermined degree of force against the shaft **112** depending upon the selective size of the o-ring **186**. In another embodiment, for example, the inside diameter of the bore **180** may be slightly smaller than the outside diameter of the shaft **112** to provide the compressive force.

In accordance with the preferred embodiment, the compression member **111** is integrally formed with the barrel **110** as a one piece unitary construction. It is contemplated that the compression member **111** and barrel **110** will be molded from suitable synthetic polymers such as ABS (Acrylonitrile butadiene styrene), nylon, Acetyl, polycarbonate, PBT (Polybutylene Terephthalate), and/or other suitable polymers.

In accordance with another embodiment, it is contemplated that the compression member **111** may be formed as a separate component from the barrel **110**, and secured thereto by any suitable means, such as mechanical, adhesive or thermal bonding. One advantage of a two piece construction allows the compression member **111** to be formed from materials different from the materials of the barrel **110**. In this regard, the separate compression member **111** can be formed from materials which have a greater degree of resiliency and/or flexibility than would generally be used for construction of the barrel **110** which requires a plurality of threads **158** for supporting rotation of the knob **108**. Constructing the compression member **111** of softer and/or more resilient materials, may enable greater control of the compressive force of the compression member against the central shaft **112**.

In accordance with other embodiments of the present invention, the compression member can be constructed from other elements and structure provided within the bore **138** at the distal end of the housing **102** which will compressively engage the central shaft **112** extending therethrough or otherwise effect retardation of its rotation. For example, as previously discussed, one embodiment may include an interference fit between the central shaft **112** and the barrel **110**, without a compression member. In this embodiment, the natural inner diameter of the barrel **110** is smaller than the outer diameter of the central shaft **112**, such that the barrel **110** is resiliently deformed from its undeformed size and/or shape when the central shaft **112** is inserted therein, providing an interference fit between the central shaft **112** and the barrel **110**. Such an interference fit enhances the frictional engagement between the barrel **110** and the central shaft **112**.

According to another embodiment, a spring-like fastener **113** may be used instead of an o-ring. (See FIG. **16**.) In the illustrative embodiment shown, the spring-like fastener **113** is an e-clip. Preferably, the spring-like fastener **113** is made of a metal, but may in other embodiments be made of any other suitable resilient material, such as a rubber, a polymer, or a plastic material, including, without limitation, the synthetic polymers disclosed above with respect to the barrel **110** and compression member **111**.

Another embodiment includes the o-ring **186** being in direct contact with the central shaft **112** and being captured by the barrel **110**, such that the o-ring **186** frictionally engages the central shaft and the barrel. In such an embodiment, the barrel **110** is capable of trapping the o-ring **186** in its relative location by virtue of the friction therebetween. (See FIG. **17**.)

A proximal portion of the central shaft **112** is fixedly attached to the proximal end **150** of the knob **108**. In accordance with one embodiment, the knob **108** is constructed from synthetic polymers such as from those which form the barrel **110**. The central shaft **112** can be constructed from suitable biocompatible metals such as stainless steel, titanium and the like. A similar metal insert **188** can be molded into the annular recess **152** formed in the proximal end **150** of the knob **108**. The shaft **112** can be welded to the insert **188** or by using other suitable fusion techniques. In accordance with another embodiment, the knob **108** can be constructed from similar metal materials as the central shaft **112**. In this event, the shaft **112** can be welded directly to the knob **108**. Based upon on the foregoing construction, rotation of the knob **108** causes corresponding rotation of the central shaft **112**.

The central shaft **112** extends through the compression member **111**, through the barrel **110**, and through the knob **108**, where a portion thereof is attached to the proximal end **150** of the knob. The proximal end **190** of shaft **112** extends through the optional bushing **114**. The bushing **114** includes an enlarged circular ring **192** which is captured in a corresponding circular groove **194** formed within the housing **102** from the first and second housing halves **104**, **106** adjacent the respect bores **128**, **134**. The bushing **114** functions as a spacer to resist rotation of the central shaft **112** which extends therethrough. In this way, the bushing **114** functions to limit the travel of the knob based on the size limitations of the corresponding adjustable prosthetic anatomical device. The distal end **196** of the central shaft **112** is rotationally supported within the bore **138** provided at the distal end of the housing **102** by the ring **164** on the barrel **110** which is captured in an annular groove **198** formed within the housing halves **102**, **106**. Additional support of the shaft **112** is provided by the compression member **111** and portions of the housing **102**.

In the assembled form of the adjustment tool **100** in accordance with one embodiment as thus far described, such as shown in FIGS. **4** and **5**, the knob **108** and barrel **110** are positioned within the opening **120** formed in the housing **102** by securing together the first and second housing halves **104**, **106**. The center shaft **112** passes through the bore **180** within the compression member **111**, through the bore **162** in the barrel **110** and through the bore **144** within the knob **108**. The knob **108** can be manipulated by ones fingers to cause its rotation about the barrel **110** by virtue of their threaded cooperation. As the knob **108** is rotated, the knob will advanced longitudinally within the opening **120** along the length of the barrel **110** to a degree related to the pitch of the threaded portions **146**, **156** of the barrel and knob. During the manipulation of the knob **108**, the barrel **110** is precluded from rotating by virtue of the projections **170** being capture within the notches **172** within the housing **102**. Rotation of the knob **108** causes rotation of the central shaft **112**, the rotation of which is retarded by the compression member **111**. Compression of the elongated members **178** of the compression member **111** is maintained by the o-ring **186**. The compression member **111** and o-ring **186** cooperate to prevent unintended rotation of the shaft. Accordingly, the shaft **112** can be rotated by a controlled amount by rotating the barrel **108**. The rotation of the shaft **112** is operative for adjusting the opening size and/or shape of an annuloplasty ring or other anatomical device when coupled thereto.

Referring to FIGS. **5**-**8**, there is shown a locking device constructed in accordance with one embodiment of the present invention generally designated by reference numeral **200**. The locking device functions in accordance with one aspect thereof to removably attach the adjustment tool **100** to the implanted prosthetic anatomical device, such as an adjustable annuloplasty ring. The annuloplasty ring is thus maintained attached to the adjustment tool while being adjusted in situ by the surgeon thereby preventing inadvertent disconnection.

The locking device as illustrated is constructed to include an elongated shaft **202** having a threaded distal end **204**, a hollow knob **206** and a hollow sleeve **208**. The knob **206** can be constructed as a unitary cylindrical body having a first portion **210** of a first diameter and a second portion **212** of a larger second diameter. The end **214** of the second portion **212** generally has a noncylindrical shaped profile such as square, rectangular, polygonal, oval, triangular or the like. An elongated bore **216** extends through the knob **206** having a smaller restricted bore **218** extending through end **214** as shown in FIG. **10**. The shaft **202** extends through the bore **216** having its end secured within the restricted bore **218**. The cylindrical first portion **210** of the knob **206** is received within a bore **220** at the proximal end **221** of the shaft **112**. The diameter of the first portion **210** is sized and shaped to enable rotation of the knob within the bore **220**. A lip **224** is formed at the juncture of the first and second portions **210**, **212** of the knob as a result of the different diameters. In accordance with the preferred embodiment, the knob **206** is constructed from surgical material such as titanium, stainless steel and the like.

The sleeve **208** as shown in FIGS. **7**, **8** and **10** can be constructed as an elongated body **226** having a through bore **228**. A configured portion **230** of the bore **228** adjacent the proximal end **232** of the sleeve **208** has a geometric shape complimentary to the geometric shape of end **214** of the knob **206**. The end **214** of the knob **206** is slidingly received within the configured portion **230** and prevented from relative rotation by virtue of the complimentary noncircular shapes of the end **214** and configured portion **230**. This construction keys the sleeve **208** to the knob **206** preventing relative rotation therebetween. The remaining portion of the bore **228** is sized and shaped to slidingly receive the remaining portions of the first and second portions **210**, **212** of the knob **206**, see FIGS. **10** and **12**.

The distal portion **234** of the sleeve **208** is provided with at least one, and preferably at least two, elongated appendages **236** each preferably having an inwardly directed locking tab **238** at their free end. The appendages **236** are formed between spaced apart elongated slots **240** or other arrangements which provide the appendages with resiliency to enable their flexing during use of the locking tool **200** as to be described hereinafter. In this regard, the sleeve **208** can be constructed from suitable synthetic polymers such as those used in the construction of the compression member **111** as described with respect to the adjustment tool **100**. In the preferred embodiment shown, two appendages **236** are provided arranged opposing one another. However, it is to be understood that a single appendage **236** provided with a locking tab **238** is contemplated, as well as more than two such appendages arranged circumferentially about the sleeve **208**.

One or more openings **242** are provided adjacent the proximal end **221** of the central shaft **112**. The openings **242** are sized, shaped and arranged to align with and receive the locking tabs **238** provided on the appendages **236**. Accordingly, in the preferred embodiment, each locking tab **238** will be associated with at least one opening **242** for releasable receipt of the locking tab therein.

Referring to FIGS. **9**-**12**, there will be described the operation of the locking device **200** in accordance with one embodiment of the present invention as thus far described. The primary function of the locking device is to provide the surgeon with the capability of releasable securing the adjustment tool **100** to an implanted prosthetic anatomical device by rotation of the knob **206**. On the other hand, the central shaft **112** has its primary function to enable adjustment of the size and/or shape of the anatomical device by rotation of the knob **108** as previously described with respect to FIGS. **1**-**4**. The sleeve **208** is adapted to slide longitudinally along the length of the knob **206** in keyed relationship whereby the locking tabs **238** on the appendages **236** are received within and released from the openings **242** on the proximal end **221** of the central shaft **112**. The sleeve **208** is keyed to the knob **206** such that when the locking device **200** is arranged in its rearward unlocked position, rotation of the sleeve effects rotation of the knob **206**, and enhance rotation of the shaft **202** which has a threaded tip **204** for releasable engagement with the anatomical device. When the sleeve **208** is arranged in its forward locked position, the locking device **200** prevents rotation of the knob **206** and shaft **202** to prevent disengagement of the adjustable tool **100** from the anatomical device.

Referring to FIGS. **9** and **10**, the locking device **200** is shown in an unlocked position accomplished by sliding the sleeve **208** rearwardly whereby rotation of the sleeve **208** causes concurrent rotation of the knob **206**, and enhance rotation of the shaft **202**. As previously described, the knob **206** is keyed to the sleeve **208** as a result of the complimentary noncircular shapes of end **214** of the knob **206** and the configured portion **230** of the bore **228** of the sleeve **208**. In the unlocked position of the locking device **200**, the locking tabs **238** on the appendages **236** are not captured within the openings **242** in the central shaft **112**. Rather, the locking tabs **238** are received about the first portion **210** of the knob **206** between the lip **224** and the proximal end **221** of the central shaft **112**. This arrangement allows the keyed sleeve **208** and knob **206** combination to freely rotate disengage from the central shaft **112**, thereby enabling rotation of shaft **202** for engagement and disengagement with the anatomical device.

The locking device **200** is shown in a locked position in FIGS. **11** and **12**. The locked position is accomplished by sliding the sleeve **208** forward longitudinally along the length of the knob **206** until the locking tabs **238** are captured within the openings **242** in the central shaft **112**. This action is facilitated by the appendages **236** being flexible and resilient so as to deflect radially outward when abutting the proximal end **221** of the central shaft **112**. The proximal end **221** of the central shaft **112** maybe provided with a chamfered edge to facilitate displacement of the appendages **236**. Accordingly, after the appendages **236** are expanded outwardly as they slide over the proximal end **221** of the central end **112**, they return to their original orientation such that the locking tabs **238** are now received within the openings **242**. The engagement of the locking tabs **238** with the openings **242** prohibit rotation of the sleeve **208**, and enhance knob **206**, thereby preventing disengagement of the adjustment tool **100** from the anatomical device being adjusted.

In accordance with another aspect of the present invention as shown in FIG. **13**, an elongated hypotube **244** is arranged concentric about shaft **202** extending through the adjustment tool **100** and into the bore **216** within the knob **206** of the locking device **200**. The end of the hypotube **244** may be secured within the bore **216** of the knob **206**, or otherwise be arranged in abutting engagement with a portion thereof. The shaft **202** extends longitudinally through an enlarged hypotube **246** which is attached to the free end of the central shaft **112**.

The distal end of the hypotube **244** can optionally be provided with a flange **248**. A compression spring **250** can be arranged extending longitudinally about a portion of the shaft **202** between the flange **248** and the proximal end of the hypotube **246**. The spring **250** is arranged in compression thereby biasing the threaded distal end **204** of the shaft **202** into a released or non-engaged position with the anatomical device. This optional arrangement, facilitates detachment of the adjustable tool **100** after adjustment of the anatomical device.

Referring to FIGS. **14** and **15**, there will now be described a locking device **252** constructed in accordance with another embodiment of the present invention. The locking device **252** includes an elongated generally cylindrical knob **254** having an elongated bore **256** extending therethrough, and a generally elongated cylindrical sleeve **258** having a bore **260** extending therethrough. The knob **254** has a distal end **262** configured to be rotationally received within the proximal end **221** of the central shaft **112**. Insertion of the knob **254** is restricted by an abutment **264** circumscribing a portion of the knob. The remaining portion of the knob is slidingly received longitudinally within the bore **260** of the sleeve **258**. A pair of spaced apart annular grooves **266**, **268** are arranged circumferentially about the knob **254** outwardly of the abutment **264**. Although the grooves are described as annular grooves, it is contemplated that the grooves may be discontinuous or that the grooves may be constructed in other forms such as openings, raised elements and the like which will be understood from the application of the grooves to be described hereinafter. The proximal end **270** of the knob is constructed in the form of a locking element **272**. The locking element **272** can be constructed as a configured member, such as a plurality of gear teeth, in the form of a noncylindrical shape such as square, polygonal, oval and the like. The end of the shaft **202** is attached to the knob **254**, such as at its proximal end **270**.

The sleeve **258** at its distal end **274** is formed to include one or more tabs **276** which extend radially inwardly. The tabs **276** may be constructed in a similar manner as the locking tabs **238** as previously described with respect to the locking device **200**. In this regard, the sleeve **258** may be provided with appendages formed by elongated slots as thus far described with respect to the locking device **200**. The tabs **276** are configured to be releasably engageable within the grooves **266**, **268** by longitudinally sliding the sleeve **258** along the length of the knob **254**.

The bore **260** of the sleeve is formed at its proximal end **278** with a nonengagement portion **280** and an inwardly provided portion forming a locking element **282**. The locking element **282** is configured to cooperate with the locking element **272** on the knob **254**. In this regard, the locking element **282** is preferably constructed as a complimentary structure, such as meshing gears, or a complimentary shaped structure. Accordingly, when the locking elements **272**, **282** are engaged, rotation of the sleeve **258** will cause rotation of the knob **254**. On the other hand, the nonengagement portion **280** is configured so as not to engage the locking element **272** of the knob **254** when received within the nonengagement portion.

As shown in FIG. **14**, the locking device **252** is arranged in a locked orientation whereby rotation of the sleeve **258** causes rotation of the knob **254**. In the locked orientation, the sleeve **258** is arranged rearwardly along the knob **254** such that the tabs **276** are received within the groove **268**, and the locking elements **272**, **282** are maintained engaged with one another. Rotation of the sleeve **258** effects rotation of the shaft **202** to allow for the attachment and disengagement of the adjustment tool **100** to an anatomical device.

The locking device **252** is shown in an unlocked orientation in FIG. **15**. In this regard, the sleeve **258** has been displaced longitudinally forward on the knob **254** whereby the tabs **276** are received within the groove **266**. In this orientation, the locking element **272** at the proximal end of the knob **270** is received within the nonengagement portion **280** of the sleeve **258**. Rotation of the sleeve **258** will not effect rotation of the knob **254**, and therefore, will not effect rotation of the shaft **202**.

As best shown in FIG. **4**, in one exemplary embodiment, housing **102** may include a scale **117**. Knob **108** may also include a pointer **109**. Pointer **109** may be arranged on knob **108** and adapted to align with scale **117**. Scale **117** and pointer **109** allow a surgeon using adjustment tool **100** to determine the degree to which the size of the adjustable annuloplasty ring has been adjusted during the annuloplasty procedure. In one embodiment, pointer **109** may be a band at least partially circumscribing knob **108**. In another embodiment, pointer **109** may include one or more arrows arranged on knob **108**. Preferably, pointer **109** is arranged adjacent a distal end of knob **108**, but may alternatively be arranged at another location along knob **108** in other embodiments. Furthermore, another embodiment may include multiple pointers **109** arranged at various positions along knob **108**.

In one embodiment, scale **117** is printed on housing **102**. In other embodiments, scale **117** may, for example, be etched, engraved, embossed, or molded to housing **102**. Scale **117** may also be raised on or recessed into housing **102**. In another embodiment, scale **117** may include an electronic display (not shown) provided on housing **102**. In another embodiment, scale **117** may be provided on one or more labels that can be permanently or temporarily affixed to housing **102**.

Scale **117** provides the surgeon with a reference to determine the degree to which the size of the adjustable annuloplasty ring has been adjusted during the procedure and whether to adjust the size of the annuloplasty ring further. By referring to scale **117**, the surgeon may determine the actual annuloplasty ring size or size relative to scale **117** at the beginning of the annuloplasty procedure and the adjustments that have been performed relative to that size throughout the procedure. The surgeon may therefore determine the degree to which the size of the adjustable annuloplasty ring has been adjusted, and may decide whether to make a further adjustment thereto. Moreover, if the surgeon decides to make a further adjustment, scale **117** may also allow the surgeon to determine the magnitude of the further adjustment that is necessary or preferred. In one embodiment, scale **117** may also indicate the desired size of the annuloplasty ring, which may be determined prior to the annuloplasty procedure, which may allow the surgeon to compare the size of the annuloplasty ring at a given time during the procedure with the predetermined desired size.

In the exemplary embodiment shown, scale **117** is a Seguin sizing scale. However, in other embodiments, scale **117** may be another type of scale. For example, in other embodiments, scale **117** may list one or more dimensions of the adjustable prosthetic anatomical device corresponding to different positions along scale **117**. In some embodiments, the dimension(s) listed on scale **117** may be the diameter, circumference, length of an anterior/posterior axis, length of a commissure-to-commissure (C/C) axis, and/or another dimension of the device. In one embodiment, scale **117** indicates the dimension(s) in millimeters. In other embodiments, scale **117** may indicate the dimension(s) in inches or any other appropriate unit of measure. Furthermore, in other embodiments, scale **117** may be a set of letters, dashes, tick marks, indicia, or other symbols indicating the relative position of pointer **109** and, therefore, the size of the adjustable prosthetic anatomical device, which may be the actual size or the size relative to scale **117**. In other embodiments, multiple tools **100** may be provided, with the scale **117** provided on each tool pertaining to a different range of sizes. In different embodiments, some of the ranges may partially overlap with one another; however, in other embodiments, multiple tools **100** may each cover separate size ranges.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

The invention claimed is:

1. A tool for adjusting the size of an adjustable annuloplasty ring, comprising:

a housing having a scale thereon configured to indicate the size of the annuloplasty ring and an opening therein;

a knob rotatable and longitudinally moveable within the opening of the housing;

a shaft coupled to the knob for rotation therewith and including a distal end adapted to engage an adjustable annuloplasty ring, wherein rotation of the shaft by the knob adjusts the size of the annuloplasty ring; and

a pointer arranged on the knob to indicate the size of the adjustable annuloplasty ring corresponding to the scale aligned with the pointer when moved longitudinally within the opening of the housing.

2. The tool according to claim **1**, wherein the scale is a Seguin sizing scale.

3. The tool according to claim **1**, wherein the scale indicates the outer diameter of the adjustable annuloplasty ring.

4. The tool according to claim **1**, wherein the scale includes a plurality of symbols indicating the magnitude of the displacement of the pointer with respect to the scale.

5. The tool according to claim **1**, wherein the pointer is arranged adjacent a distal end of the knob.

6. The tool according to claim **1**, wherein the pointer comprises a band at least partially circumscribing the knob.

7. The tool according to claim **1**, wherein the scale is printed on the housing.

8. The tool according to claim **1**, wherein the scale is molded into the housing.

9. The tool according to claim **1**, further comprising a threaded barrel coupled to the housing;

wherein the knob includes internal threads adapted to engage the threaded barrel such that rotation of the knob relative to the threaded barrel causes the knob to move longitudinally within the opening with respect to the barrel.

10. The tool according to claim **9**, wherein the knob comprises an elongated cylindrical body, and the thread barrel comprises an externally threaded elongated cylindrical body; wherein rotation of the knob causes the knob to move longitudinally within the opening of the housing along the barrel.

11. The tool according to claim **10**, wherein the housing includes a confining opening within a distal end of the housing, and wherein the barrel includes a circumscribing ring at a distal end of the barrel received within the confining opening for preventing longitudinal movement of the barrel within the opening in the housing.

12. The tool according to claim **9**, wherein the housing includes at least one notch, and wherein the barrel includes at least one protrusion received within the at least one notch for preventing rotation of the barrel within the opening in the housing.

13. The tool according to claim **9**, wherein the barrel includes a compression member through which the shaft extends for restricting unintended rotation of the shaft.

14. The tool according to claim **13**, further including an element engaging the compression member for creating frictional engagement of the compression member with the shaft for restricting unintended rotation of the shaft.

15. The tool according to claim **1**, further comprising an elongated hypotube arranged substantially concentrically about the shaft.

16. The tool according to claim **1**, wherein the opening comprises a central elongated opening within the housing, the housing including proximal and distal ends which have through bores through which the shaft extends.

17. A tool for adjusting the size of an adjustable annuloplasty ring, the tool comprising:

a housing having a scale thereon to indicate the size of the annuloplasty ring and an opening therein, the housing including a proximal end and a distal end;

a threaded barrel coupled to the housing and extending along at least a portion of the length of the housing within the opening;

a knob rotatably disposed about the threaded barrel and longitudinally moveable within the opening along the barrel, the knob having threads adapted to engage the threaded barrel;

a shaft extending within the knob supported within the housing and being coupled to the knob for rotation with the knob, wherein rotation of the shaft by the knob adjusts the size of the annuloplasty ring;

an adjustment head arranged on a distal end of the shaft and being adapted to engage an adjustable annuloplasty ring; and

a pointer arranged on the knob and adapted to align with the scale when moved longitudinally within the opening of the housing.

18. The tool according to claim **17**, wherein the knob comprises an elongated cylindrical body, and the thread barrel comprises an externally threaded elongated cylindrical body; wherein rotation of the knob causes the knob to move longitudinally within the opening of the housing along the barrel.

19. The tool according to claim **18**, wherein the housing includes a confining opening within the distal end, and wherein the barrel includes a circumscribing ring at a distal end of the barrel received within the confining opening for preventing longitudinal movement of the barrel within the opening in the housing.

20. The tool according to claim **17**, wherein the housing includes at least one notch, and wherein the barrel includes at least one protrusion received within the at least one notch for preventing rotation of the barrel within the opening in the housing.

21. The tool according to claim **17**, wherein the barrel includes a compression member through which the shaft extends for restricting unintended rotation of the shaft.

22. The tool according to claim **21**, further including an element engaging the compression member for creating frictional engagement of the compression member with the shaft for restricting unintended rotation of the shaft.

23. A method of adjusting the size of an adjustable annuloplasty ring, comprising:

engaging an adjustable annuloplasty ring with an adjustment tool, the adjustment tool comprising:

a housing having a scale thereon and an opening therein;

a knob rotatably disposed within the opening of the housing;

a pointer arranged on the knob to align with the scale; and

a shaft coupled to the knob for rotation therewith and including a distal end adapted to engage the adjustable annuloplasty ring;

rotating the knob for moving the knob longitudinally within the opening relative to the housing such that the pointer aligns with the scale; and

determining the size of the adjustable annuloplasty ring corresponding to the scale with which the pointer aligns.

24. The method according to claim **23**, further comprising disengaging the adjustment tool from the adjustable annuloplasty ring when the size of the adjustable annuloplasty ring corresponds to a predetermined desired size.

25. The method according to claim **23**, further comprising moving the knob relative to the housing to adjust the size of the adjustable annuloplasty ring after determining the size of the adjustable annuloplasty ring if the size of the adjustable annuloplasty ring does not correspond to a predetermined desired size.

26. The method according to claim **23**, wherein the scale is a Seguin sizing scale.

27. The method according to claim **23**, wherein the pointer indicates the outer diameter of the adjustable annuloplasty ring corresponding to the scale aligned with the pointer.

28. A method of adjusting the size of an adjustable annuloplasty ring, comprising:

engaging an adjustable annuloplasty ring with an adjustment tool, the adjustment tool comprising:

a housing having a scale thereon and an opening therein, the housing including a distal end and a proximal end,

a threaded barrel coupled to the housing within the opening,

a knob rotatably disposed about the threaded barrel, the knob including threads adapted to engage the threaded barrel,

a shaft extending within the knob supported within the housing, the shaft being coupled to the knob for rotation therewith,

an adjustment head arranged on the shaft and being adapted to engage the adjustable annuloplasty ring, and

a pointer arranged on the knob and adapted to align with the scale;

rotating the knob such that the shaft and the adjustment head thereof rotate with respect to the threaded barrel and such that the knob is displaced along a longitudinal direction of the threaded barrel within the opening; and

determining the adjustment to the size of the adjustable annuloplasty ring resulting from the rotation of the adjustment head and location of the pointer relative to the scale resulting from the displacement of the knob.

29. The method according to claim **28**, further comprising disengaging the adjustment tool from the adjustable annuloplasty ring when the size of the adjustable annuloplasty ring corresponds to a predetermined desired size.

30. The method according to claim **28**, further comprising moving the knob relative to the housing to adjust the size of the adjustable annuloplasty ring if the size of the adjustable annuloplasty ring does not correspond to a predetermined desired size.

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